

DECLARATION FOR PATENT APPLICATION

As the below-named inventors, we hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first inventor of the subject matter that is claimed and for which a patent is sought on the invention entitled STEROIDOGENIC FACTOR-1 PROTEIN VARIANTS AND METHODS OF MAKING SAME, the specification of which

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			as F	lppli	Lcat	ion S	Seri	al	No.	10/	61	6,897		
			(Att	orne	еу С	lient	-Ma	tte	r N	lo. 6	67	78-120)		
and	was	amended	l on	(or	ame	nded	thr	oug	h)	-		·		
										(if	ap	plicable)		

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment(s) referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to myself to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

Under Sec. 1.56, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information,

Ingraham and Krylova

Serial No.:

10/616,897 July 9, 2003

Filed: Page 2

a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (a) Opposing an argument of unpatentability relied on by the U.S. Patent and Trademark Office, or (b) Asserting an argument of patentability.

I hereby claim the benefit under Title 35, United States Code, § 119(e) of the United States provisional application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information that is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 that became available between the filing date of the prior application(s) listed below and the filing date of this non-provisional application:

Application Serial No. Filing Date Status
60/395,371 July 12, 2002 Abandoned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may

Ingraham and Krylova

Serial No.:
Filed:

10/616,897 July 9, 2003

Page 3

jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor:

Holly A. Ingraham

Inventor's signature:

Date:

Residence:

San Francisco, California, U.S.A.

Citizenship:

United States of America

Mailing Address:

50 Clifford Terrace

San Francisco, California 94117

U.S.A.

Ingraham and Krylova

Serial No.: 10/616,897 Filed:

July 9, 2003

Page 4

Full name of second inventor:

Irina Krylova

Inventor's signature: _

Residence:

Oakland, California, U.S.A.

Citizenship:

United States of America

Mailing Address:

543 42nd Street

Oakland, California 94609

U.S.A.



PATENT

Client-Matter No.: 66778-120

Applicant:

Ingraham and Krylova

Serial No.:

10/616,897

Filed:

July 9, 2003

For:

STEROIDOGENIC FACTOR-1 PROTEIN VARIANTS AND

METHODS OF MAKING SAME

Group:

Unassigned

Examiner:

Unassigned

POWER OF ATTORNEY BY ASSIGNEE AND EXCLUSION OF INVENTOR(S) UNDER 37 C.F.R. 3.71

Dear Sir:

The undersigned assignee of the entire interest in the above-identified subject application hereby appoints:

CATHRYN CAMPBELL, Registration No. 31,815; DAVID A. GAY, Registration No. 39,200; ANDREA L. GASHLER, Registration No. 41,029; DEBORAH L. CADENA, Registration No. 44,048; ASTRID R. SPAIN, Registration No. 47,956; PAMELA M. GUY, Registration No. 51,228; and MELODY E. CLARK, Registration No. 51,566

as its attorney(s) to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith, said appointment to be to the exclusion of the inventors and their attorney(s) in accordance with the provisions of 37 C.F.R. 3.71.

Ingraham and Krylova

Serial No.: Filed:

10/616,897 July 9, 2003

Atty Docket:

66778-120

Page 2

An assignment of the entire interest in the above-identified subject application:

[] was recorded on [date] at reel/frame [reel/frame].

[X] is submitted herewith for recording.

Please direct all telephone calls to Cathryn Campbell, at 858-535-9001 and all correspondence relative to said application to the following address:

McDERMOTT, WILL & EMERY
4370 La Jolla Village Drive
7th Floor

San Diego, California 92122 USA

Dated:

August 14, 2003

ASSIGNEE:

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

Signature:

Typed Name: Susan Y. Nakashima

Title:

Business Manager UCSF OTM

Office of Technology Transfer the President A.N.

1111 Franklin Street, 12 Floor

Oakland, CA 94607-5200



PATENT

Client-Matter No.: 66778-120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
 Ingraham and Krylova

Serial No. 10/616,897

Filed:

July 9, 2003

For: STEROIDOGENIC FACTOR-1
PROTEIN VARIANTS AND
METHODS OF MAKING SAME

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

SMALL ENTITY STATEMENT

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

(1) Individual person:

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

(2) Small business concern:

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

"Business concern" means individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative. If the concern is a joint

Inventor: Ingraham and Krylova

Serial No.: 10/616,897 Filed: July 9, 2003

Page 2

venture, participation by foreign business entities may not be more than 49%. 13 C.F.R. § 121.105.

The "number of employees" is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months. "Employees" includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

(3) Nonprofit organization:

A university or other institution of higher education located in any country. § 1.27(a)(3)(ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B),(D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. \$ 1.27(a)(3)(ii)(C),(D).

Inventor: Ingraham and Krylova

Serial No.: 10/616,897 Filed: July 9, 2003

Page 3

Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).

I hereby assert that I am empowered to sign on behalf of the party identified below ("Party"). Persons empowered to sign include, but are not limited to, an inventor him- or herself or an authorized officer of an assignee or licensee. See § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. The other party having rights in the invention is: The Regents of the University of California. Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

Ingraham and Krylova

Serial No.: Filed:

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I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(q).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

Scott M. Thacher

Orphagen Pharmacuticals 3857 Birch Street, Suite 492 Newport Beach, California 92660



PATENT

Client-Matter No.: 66778-120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ingraham and Krylova

Serial No. 10/616,897

Filed: July 9, 2003

For: STEROIDOGENIC FACTOR-1 PROTEIN VARIANTS AND METHODS OF MAKING SAME

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

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(1) Individual person:

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

(2) Small business concern:

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

"Business concern" means individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative. If the concern is a joint venture, participation by foreign business

Ingraham and Krylova

Serial No.: Filed:

10/616,897 July 9, 2003

Page 2

entities may not be more than 49%. 13 C.F.R. § 121.105.

The "number of employees" is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months. "Employees" includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

(3) Nonprofit organization:

A university or other institution of higher education located in any country. § 1.27(a)(3)(ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B),(D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C),(D).

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Inventor: Ingraham and Krylova

Serial No.: 10/616,897 Filed: July 9, 2003

Page 3

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I hereby assert that I am empowered to sign on behalf of the party identified below ("Party"). Persons empowered to sign include, but are not limited to, an inventor him- or herself or an authorized officer of an assignee or licensee. See § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed—and is under no obligation under contract or law to do so—any rights in the invention to any other party that would not qualify as a Small Entity. The other party having rights in the invention is: Orphagen Pharmaceuticals. Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

Ingraham and Krylova

Serial No.: Filed:

10/616,897 July 9, 2003

Page 4

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I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

August 14, 2003

Date

Name: / Susan Y. Nakashima

Title: ____Business Manager UCSF OTM

The Regents of the University of California Office of Technology Transfer the President (SW) 1111 Franklin Street, 12th Floor Oakland, California 94607-5200



STATEMENT UNDER 37 C.F.R. § 3.73(b)

Title of Application: STEROIDOGENIC FACTOR-1 PROTEIN

VARIANTS AND METHODS OF MAKING SAME

Application Ser. No.: 10/616,897

Filed: July 9, 2003

Inventor(s):
Ingraham and Krylova

Attorney Client-Matter No.: 66778-120

The Regents of the University of California, a University, states that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of an assignment from the inventors of the application. A copy of the executed assignment, submitted for recording, is attached hereto as documentary evidence of the chain of title to the assignee.

The undersigned is empowered to sign this statement on behalf of the assignee.

Date: August 14, 2003

Signature: Susan Y. Nakashima

Name: Susan Y. Nakashima

Title: Business Manager UCSF OTM

ASSIGNMENT



U.C. Case No.: <u>SF2001-103-2</u> MWE Client-Matter No.: <u>66778-120</u>

For good and valuable consideration, the receipt of which is hereby acknowledged, ASSIGNOR(S),

1. Holly A. Ingraham

2. Irina Krylova

hereby sells, assigns and transfers to ASSIGNEE, The Regents of the University of California, A California Corporation, having its statewide administrative offices located at 1111 Franklin Street, 12th Floor, Oakland, CA´94607-5200, and the successors, assigns and legal representatives of the ASSIGNEE all of its right, title and interest for the United States and its territorial possessions and in all foreign countries in and to, any and all improvements which are disclosed in the invention entitled:

and which is found in

- a) ___ U.S. provisional application filed herewith and listing the above named persons as inventors
- (b) ____ U.S. patent application filed herewith and listing the above named persons as inventors
- (c) X U.S. application serial no. 10/616,897, filed on July 9, 2003
- (d)____ U.S. Patent No.:

, issued

and any legal equivalent thereof in a foreign country, including the right to claim priority and, in and to, all Letters Patent to be obtained for said invention by the above application or any continuation, division, continuation—in—part, extension, conversion to 35 USC 111(a) or substitute thereof, and any reissue, reexamination or extension of said Letters Patent and all rights under all International Conventions for the Protection of Industrial Property;

<u>ASSIGNOR(S)</u> hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment;

Ingraham and Krylova

Serial No.: Filed:

10/616,897 July 9, 2003

Page 2

ASSIGNOR(S) further covenants that ASSIGNEE will, upon its request, be provided promptly with all pertinent facts and documents relating to said invention and said Letters Patent and legal equivalents as may be known and accessible to ASSIGNOR and will testify as to the same in any interference, litigation, or proceeding relating thereto and will promptly execute and deliver to ASSIGNEE or its legal representative any and all papers, instruments or affidavits required to apply for, obtain, maintain, issue or enforce said application, said invention and said Letters Patent and said equivalents thereof which may be necessary or desirable to carry out the purposes thereof. An attorney of record is authorized and requested by the execution of this assignment to insert into this assignment the filing date and serial number of said application when officially known.

AND the <u>ASSIGNOR(S)</u> requests the Director of the United States Patent and Trademark Office to issue said Letters Patent of the United States and any reissue or extension thereof to the ASSIGNEE, The Regents of the University of California.

Executed this

Signatures of Inventor(s)

1 day of December, 2003

11 day of December, 2003

Ikrylova

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State of California	` <u> </u>
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On DECEMBER 11, 2003, before me, 1	Name (a) of Signer(s) NOTATION ROTATION NOTATION NOT
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	subscribed to the within instrument and
	acknowledged to me that he/she/they executed
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	capacity(i es), and that by his/her/their
HELEN E. WOOLRIDGE	signature(s) on the instrument the person(s), or
Commission # 1250497 Notary Public - California	the entity upon behalf of which the person(e)
San Francisco County	acted, executed the instrument.
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Capacity(ies) Claimed by Signer Signer's Name:	RIGHT THUMBPRINT
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County of SW FANCESO On December 11,2002, before me, Helicol E would be with the personally appeared Personally appeared Personally appeared Personally known to me proved to me on the basis of satisfactory evidence to be the personally known to me proved to me on the basis of satisfactory evidence to be the personally known to me proved to me on the basis of satisfactory evidence to be the personally known to me proved to me on the basis of satisfactory evidence to be the personally known to me proved to me instrument and acknowledged to me that he/her/their authorized capacity(tes), and that by his/her/their signature(s) on the instrument the person(s) of the entity upon behalf of which the person(s) of the entity upon behalf of which the person(s) acted, executed the instrument. WITNESS my hand and official seal. Place Notary Seal Above OPTIONAL Though the information below is not required by the persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document. Description of Attached Document Title or Type of Document Signer(s) Other Than Named Above: Mumber of Pages: Partner— Unimited General Attorney in Fact Trustee Guardian or Conservator Other:		
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Commission # 1250497 Notary Public - California San Francisco County My Comm. Expires Jan 18, 2004 Place Notary Seal Above WITNESS my hand and official seal. WITNESS my ha	HELEN E. WOOLRIDGE	signature(s) on the instrument the person(s), or
San Francisco County My Comm. Expires Jan 18, 2004 Place Notary Seal Above OPTIONAL Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document. Description of Attached Document Title or Type of Document: Document Date: Number of Pages: Number of Pages: Number of Pages: Partner — Dimited Deneral Attorney in Fact Trustee Guardian or Conservator Other:	Commission # 1250497	the entity upon behalf of which the person(s)
My Comm. Expires Jan 18, 2004 Place Notary Seal Above OPTIONAL Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document. Description of Attached Document Title or Type of Document: Document Date: Number of Pages: Number of Pages: Partner — Dimited by Signer Signer's Name: Partner — Limited General Attorney in Fact Trustee Guardian or Conservator Other:	Notary Public - California	acted, executed the instrument.
Place Notary Seal Above OPTIONAL Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document. Description of Attached Document Title or Type of Document: Document Date: Number of Pages: Signer(s) Other Than Named Above: HOLLY AND FINANT Capacity(ies) Claimed by Signer Signer's Name: Individual Corporate Officer — Title(s): Partner — Limited — General Attorney in Fact Trustee Guardian or Conservator Other:	San Hancisco Courty My Comm Expires Jan 18, 2004	ANTENERO LA LA LA LA MARIA LA CALLA
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Signer's Name: Individual Corporate Officer — Title(s): Partner — Limited General Attorney in Fact Guardian or Conservator Other:		· _ 9
☐ Individual ☐ Corporate Officer — Title(s): ☐ Partner — ☐ Limited ☐ General ☐ Attorney in Fact ☐ Trustee ☐ Guardian or Conservator ☐ Other:	•	
□ Corporate Officer — Title(s): □ Partner — □ Limited □ General □ Attorney in Fact □ Trustee □ Guardian or Conservator □ Other:	☐ Individual	
☐ Attorney in Fact ☐ Trustee ☐ Guardian or Conservator ☐ Other:	☐ Corporate Officer — Title(s):	
☐ Trustee ☐ Guardian or Conservator ☐ Other:	☐ Partner — ☐ Limited ☐ General	
☐ Guardian or Conservator ☐ Other:	☐ Attorney in Fact	
□ Other:		
	 ,	
Signer Is Representing:		
	Signer Is Representing:	
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State of California	
County of SAN FRANCISCO	\$ 55.
Sounty or	 J
On Jecuber 11, 2003, before me, He	Name and Title of Officer (e.g., "Jane Doe, Notary Public") INGRAHAM Name(S), of Signer(s)
personally appeared	N INGRAHAM
	Name(s) or signer(s)
	personally known to me proved to me on the basis of satisfactory
•	evidence
	evidence
	to be the person(s) whose name(s) is/are
	subscribed to the within instrument and
	acknowledged to me that he/she/they executed
,	the same in his/her/their authorized capacity(ies), and that by his/her/their
minima ?	signature(s) on the instrument the person(s) or
HELEN E. WOOLRIDGE Commission # 1250497	the entity upon behalf of which the person(s)
Notary Public - California	acted, executed the instrument.
San Francisco County	
My Comm. Expires Jan 18, 2004	WITNESS my hand and official seal.
	place went
Place Notary Seal Above	Signature of Notary Public
—	PTIONAL
Though the information below is not required by law and could prevent fraudulent removal an	w, it may prove valuable to persons relying on the document ad reattachment of this form to another document.
Description of Attached Document	7 400/10.78
Title or Type of Document:	ARATION FOR PATENT APPLICATION
	4 PMU
Document Date:	Number of Pages:
Signar(s) Other Than Named Ahove: IRE	Number of Pages: 4 fry U
Signer(s) Other Than Named Above.	
Capacity(ies) Claimed by Signer	
Signer's Name:	RIGHT THUMBPRINT OF SIGNER
☐ Individual	
☐ Corporate Officer — Title(s):	,
☐ Faither — ☐ Limited ☐ General	
□ Attorney in Fact □ Trustee	
☐ Trustee ☐ Guardian or Conservator	
Other:	
•	
Signer Is Representing:	

Out to Codifferent	
State of California	60
County of Snu Francisco	
On December 11,2003, before me, 14	Name and Title of Officer (e.g., "Jane Doe, Notary Public") KRY LOVA Name(s) of Signer(s)
personally appeared	= KRY LOVA
•	Name(s) or Signer(s)
	□ personally known to me□ proved to me on the basis of satisfactory
•	evidence
	S
	to be the person(s) whose name(s) is/are subscribed to the within instrument and
	acknowledged to me that he/she/they executed
1 - 2	the same in his/her/their authorized
	capacity(ies), and that by his/her/their
HELEN E. WOOLRIDGE Commission # 1250497	signature(s) on the instrument the person(s), or
Notary Public - California	the entity upon behalf of which the person(s) acted, executed the instrument.
San Francisco County My Comm. Expires Jan 18, 2004	adica, excepted the metallions
My Confin. Expired John 10, 2004	WITNESS my hand and official seal.
	Helen & Wordy
Place Notary Seal Above	Signature of Notary Public .
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and could prevent fraudulent removal an	id reattachment of this form to another document.
Description of Attached Document	1 - 2 - 3 - 71
Title or Type of Document:	CLAPATION POIL MATERIA
	CLAPATION FOR PATENT Application
Document Date.	Nulliper of Fades.
Signer(s) Other Than Named Above:	LY AND INGRAHAM
Capacity(ies) Claimed by Signer	
Signer's Name:	RIGHT THUMBPRINT OF SIGNER
Individual	Top of thumb here
☐ Corporate Officer — Title(s):	
☐ Attorney in Fact	
☐ Trustee	
☐ Guardian or Conservator	
Other:	deutorista.
Signer Is Representing:	